

Office of Environmental Health Hazard Assessment



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Arnold Schwarzenegger
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MEMORANDUM

TO: Gerald W. Bowes, Ph.D., Manager
Toxicology and Peer Review Section
State Water Resources Control Board
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FROM: David M. Siegel, Ph.D., Chief, (Original Signed)
Integrated Risk Assessment Branch
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DATE: November 30, 2007

SUBJECT: REQUEST FOR EXTERNAL PEER REVIEW OF AN ASSESSMENT OF
CHILDREN'S EXPOSURE TO SURFACE METHAMPHETAMINE
RESIDUES AND DEVELOPMENT OF A RISK-BASED CLEANUP
STANDARD FOR SURFACE METHAMPHETAMINE CONTAMINATION

This memorandum is my request for you to initiate the process to obtain reviewers through the University of California to provide external peer review of a report assessing children's exposure to methamphetamine residues on indoor surfaces, and describing the development of a risk-based cleanup standard for methamphetamine-contaminated surfaces. This analysis was developed by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) staff. The present request is only for the review of the exposure assessment and calculation of a surface reference exposure level (REL). A proposed methamphetamine reference dose (RfD)* was developed in a separate report and is also undergoing external peer review.

*RfDs are doses (expressed in units of mg/kg-day) at or below which adverse health effects are not likely to occur. A central assumption is that a threshold exists below which adverse effects will not occur in a population; however, such a threshold is not observable and can only be estimated. An RfD is a quantitative estimate of the lowest dose at which a toxic effect will occur, combined with uncertainty factors that account for variability in sensitivity in the human population and uncertainty in the toxicity database. In the report addressed in this memorandum, the estimate of exposure to methamphetamine residues on surfaces was combined with the RfD for methamphetamine to generate a surface REL.

California Environmental Protection Agency

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption.

Under the provisions of Health and Safety Code Section 25354.5, OEHHA, in cooperation with the Cal/EPA Department of Toxic Substances Control (DTSC), is required to prepare documentation supporting a risk-based exposure standard (i.e., a “cleanup level”) for methamphetamine residues on surfaces to ensure protection of the health of all persons who subsequently occupy a residence that formerly was a clandestine methamphetamine laboratory. The cleanup standard will be developed by DTSC and based on the surface REL. To ensure that the cleanup standard for methamphetamine is health protective, both the RfD and the exposure assessment must be scientifically defensible.

We anticipate having a draft document describing development of an exposure assessment and surface REL available for external peer review by early December 2007. We request that the review be completed within 30 days upon receipt of the report. Public review of the document will be scheduled for early January 2008.

We believe that the desirable areas of expertise for peer reviewers of this assessment should be the following, in order of importance:

1. Human Risk Assessment: exposure assessment
2. Exposure Modeling: surface to skin

There are three attachments to this memorandum. Attachment I summarizes development of the exposure assessment and the surface REL. Attachment II identifies the scientific issues to be evaluated by external the peer-reviewers. Attachment III lists the individuals involved in the development of (1) the exposure assessment, and (2) the RfD (which is undergoing separate external peer review).

If you have any questions, please contact me at 916-322-5624 or at, dsiegel@oehha.ca.gov. The staff contact for this proposal is Dr. Charles Salocks, who can be reached at 916-323-2605 or at, csalocks@oehha.ca.gov. Thank you for your consideration of this request.

Attachments (3)

cc: George V. Alexeeff, Ph.D.
Deputy Director for Scientific Affairs

Charles Salocks, Ph.D.
Integrated Risk Assessment Branch

John Ferderer
Contracts & Business Services Branch

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Attachment I: Summary of the analysis of children's exposure to methamphetamine residues on indoor residential surfaces and the rationale for development of a surface REL for methamphetamine

I. Background

The clandestine synthesis of methamphetamine is a growing public health and environmental concern. It is estimated that synthesis of one pound of methamphetamine generates six or more pounds of hazardous chemicals and materials. In addition to concerns over the health and well being of peace officers and public health officials, there is increasing concern over potential health impacts on the public and unknowing inhabitants, including children and the elderly, who subsequently occupy dwellings where illegal drug labs have been located. To address these health concerns, the provisions of Health and Safety Code Section 25354.5 require that the Office of Environmental Health Hazard Assessment (OEHHA) develop a risk-based assessment for methamphetamine that the Department of Toxic Substances Control (DTSC) can use to set a cleanup standard. The standard would ensure protection of the health of all persons who subsequently occupy a former clandestine methamphetamine lab.

II. Rationale

From the point that is initially established through its ultimate re-occupancy, a clandestine methamphetamine lab goes through four phases that vary with the nature operations, the chemicals present, the exposure pathways, and the potentially exposed populations. The four phases may generally be described as

- Operational: clandestine synthesis and use of methamphetamine
- Discovery & Removal: the lab is "busted" (discovered by law enforcement) and bulk chemicals and equipment are removed
- Remediation & Verification: samples are collected to characterize the distribution of contaminants within the residence, the contaminants are remediated, and samples are collected to verify that residual contaminant levels are below target cleanup standards
- Re-Occupancy: a new group of residents occupies the former clandestine lab

Each phase represents a distinct exposure scenario with different primary contaminants, contaminant sources, exposure pathways and potentially exposed populations. During the first two phases, inhalation of airborne contaminants (such as methamphetamine, acidic and corrosive gases, and phosphine) probably represents the greatest hazard. Once the primary sources¹ of airborne contaminants have been physically removed, secondary sources may still remain in the residence. Secondary sources include materials contaminated by chemical spills and "soft"

¹ Primary sources include reaction vessels, solvents stored in their original containers, solvents transferred to other containers, and tanks of compressed gases such as ammonia and hydrogen chloride.

media (such as upholstered furniture, drapes, carpet and wallboard) that have absorbed volatile contaminants during the operational phase of the clandestine laboratory. Re-release (or “off-gassing”) of volatile chemicals that have been absorbed by soft media probably represents the primary inhalation hazard during cleanup and verification activities. For reasons discussed in the document, we assume that airborne contaminants have largely dissipated by the time the residence is ready for re-occupancy. Thus, the significance of inhalation as a pathway of exposure declines markedly as the laboratory progresses through these four phases.

Non-volatile compounds, such as the hydrochloride salt of methamphetamine, represent another general class of contaminants encountered at clandestine labs. Methamphetamine has been detected on hard and soft interior surfaces at former labs and appears to persist for months or years. Pathways of exposure to these compounds include dermal absorption following skin contact with contaminated surfaces, and ingestion following skin contact and subsequent hand-to-mouth activities. With few exceptions, states have adopted remediation procedures for former clandestine labs that focus exclusively on methamphetamine levels, and the target remediation goal is usually based on analytical detection limit for the drug. Therefore, the magnitude of exposure to surface methamphetamine residues – and the consequent health risk – is controlled by the target remediation goal for methamphetamine.

III. Development of the Exposure Assessment and Surface REL

The objective of this report is to describe the processes for assessing the exposure to surface methamphetamine residues, so that potential health hazards may be controlled by establishing a clean-up standard that ensures that total exposure via all complete pathways does not exceed the RfD for methamphetamine. The exposure estimates are based on a re-occupancy scenario (the fourth phase described in section II), with very young children (approximately 6 months to 2 years of age) as the sub-population of greatest concern. While young children *may* be more sensitive to methamphetamine, they are the target population for this analysis primarily because age-specific behaviors – such as frequent contact with the floor and frequent hand-to-mouth activity – lead to greater exposure than any other age group.

Attachment II: Description of Scientific Issues to be Addressed by Peer Reviewers

The statute mandate for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, judgment, methods and practices. We request that it be each reviewer's responsibility to make this determination for each of the following issues that constitute the scientific basis of the proposed methodology. An explanatory statement is provided for each issue to focus the review. For those work products which are not proposed rules, as is the case here, reviewers must measure the quality of the product with respect to the same exacting standard as if it was subject to Health and Safety Code Section 57004.

While developing the analysis of children's exposure to surface methamphetamine residues and estimating an REL for methamphetamine on interior residential surfaces, staff identified a number of key issues. These are issues on which staff would especially appreciate review and comments.

1. Exposure scenario assumptions

Given that the available data on the distribution and persistence of contaminants in former clandestine methamphetamine labs are extremely limited, the analysis relies on several assumptions concerning the exposure scenario. In general, these assumptions were intended to be conservative – that is, they lead to estimates of exposure that are higher than otherwise would have been calculated.

2. Identification of 6-month to 2-year-old children as the “most exposed” population

The target population for this analysis was children in the age of 6 months to 2 years. Age-specific information and data suggest that these children are more likely to be exposed to contaminants on indoor surfaces than children in other age ranges. This conclusion is supported by age-specific behavior data (e.g., amount of time spent on the floor and frequency of hand-to-mouth activity).

3. Exposure estimation models

Two methods developed by the U.S. EPA were used to estimate children's exposure to surface methamphetamine residues: the 1997 Standard Operating Procedures (SOPs) for residential exposure assessment, and the 2007 SHEDS-Multimedia model. Both models were developed to estimate exposure to residues of pesticides applied indoors.

4. Assumptions used to run SHEDS-Multimedia

In addition to the assumptions that were used to characterize the exposure scenario, several additional assumptions were required to run SHEDS-Multimedia. These assumptions were

needed due to a lack of chemical- and scenario-specific information and data and generally led to higher estimates of exposure than would have been calculated otherwise.

5. Exposure parameter values adopted for SHEDS-Multimedia

SHEDS-Multimedia requires values (point estimates or distributions) for dozens of exposure parameters. A detailed table that lists input parameters and provides detailed rationale for each value or distribution used in the model was included in the report. Final values and distributions were based on published research reports, unpublished reports, and consultation with Drs. Graham Glen and Luther Smith of Alion Science and Technology, U.S. EPA's primary contractor for development of SHEDS-Multimedia.

6. Use of exposure estimates from SHEDS-Multimedia to calculate a surface REL

Studies of early childhood exposure to surface contaminants are limited. Nevertheless, the algorithms and parameter values used in the SOPs generate screening level estimates of exposure that appear to be unreasonably high. In contrast, SHEDS-Multimedia is data intensive, relying on time-location-activity diaries compiled by the U.S. EPA's Consolidated Human Activity Database (CHAD). Consequently, the surface REL was calculated using the exposure estimates generated by SHEDS-Multimedia.

Reviewers are not limited to addressing only the specific issues presented above, and are asked to contemplate the broader perspective.

- (a) In reading the proposed analysis of childhood exposure to surface methamphetamine residues, are there any additional scientific issues that are part of the scientific basis of the exposure assessment and proposed surface REL that are not described above?
- (b) Taken as a whole, are the exposure analysis and proposed surface REL based upon sound scientific knowledge, methods, and practices?

The preceding guidance is intended to ensure that reviewers have an opportunity to comment on all aspects of the scientific basis of the exposure assessment and proposed surface REL. At the same time, reviewers also should recognize that the OEHHA has a legal obligation to consider and respond to all feedback on the scientific portions of the report. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central elements being proposed.

Attachment III: Individuals Involved in the Development of the Exposure Assessment and Calculation of a Surface REL.

There were several individuals both within and outside of State service who were involved in or consulted with during the development of the exposure assessment and surface REL.

OEHHA and DTSC staff have worked with the individuals identified below to characterize the dermal absorption of methamphetamine and estimate children's exposure to methamphetamine residues on indoor surfaces using the USEPA's SHEDS-Multimedia model.

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